In re Application of: Dan ROTTENBERG et al
Serial No.: 10/597,666
Filed: June 20, 2007
Office Action Mailing Date: March 28, 2008

Examiner: Susan Shan SU
Group Art Unit: 4193
Attorney Docket: 34955

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 1-20 are currently pending in this Application.

Claims 1-20 have been rejected under 35 U.S.C. § 102.

Claims 2, 7, and 20 have been cancelled herewith.

Claims 1, 4, 6, 10, 11, 17, and 19 have been amended herewith.

Interview

The Applicants thanks the Examiner for taking the time to discuss the present office action with the Applicant in the interview on July 31, 2008. Pursuant to MPEP section 713.04, the Summary of Record of the interview is as follows:

> "Attorney has suggested an amendment to the independent claims to incorporate the limitation of the original claim 2 using the language of paragraph [045], i.e. the shunt is kept constantly ajar. Examiner recognizes that such an amendment would overcome the Wolf reference and will take the amendment into full consideration and provide a new search upon its submission.
>
> The Examiner also pointed out that lumen is defined to be the cavity within a tubular structure and the atria of a heart are not tubular, so they cannot be considered to be lumens. Thus, Applicants' claims should be amended to correspond and be supported by the specification."

For convenient reference, the Applicant notes that the first paragraph above relates to independent claims 1, 11, and 17, and the second paragraph above relates to claims 1-10 and 17-19.

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Amendments To The Specification and Drawings

The Examiner objected that some terms used in paragraph [0036] of the specification, and as reflected in FIGS. 1B – 1I, were "unclear, inexact or verbose" within the meaning of 35 U.S.C. 112. In particular, the Examiner suggested "that the numbering of the same features should be given the same number, such as "shunt 122" should be changed to - - shunt 107 - - or - - shunt 107B …". The Applicant has carefully considered the Examiner's suggestion and made the following amendments:

- in the drawings, FIG. 1A has been amended by changing number "107" to "122"; and

- in the specification, references to "shunt 107" in paragraphs [0036], [0037], and [0044] have been changed to "shunt 122".

As a result of the above amendments the shunt shown in FIGS. 1A-1I and described in corresponding portions of the description is now uniformly referred to as "shunt 122".

The Examiner also objected under 35 U.S.C. 112 to the numbering of a feature in paragraph [0048]. In response to the Examiner's request the Applicant has amended paragraph [0048] by removing the words "flow regulation", so that element 175 now refers to "a cap, valve opening, valve stem, or other mechanism". It is submitted that as a result of the amendment there is no conflict between FRM 108 and cap or mechanism 175.

The Applicant respectfully suggests that none of the above amendments to the specification and drawings add new matter to the application, and further suggests that as a result of the above amendments the specification is now in compliance with the requirements of 35 U.S.C. 112.

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Priority

The Examiner has advised that "priority claimed of Provisional Application 60/541,267 filed 03 February 2004 is not entered because it is more than one year before the filing of the PCT application". In the same paragraph the Examiner notes that the PCT application, PCT/IL05/000131, was "filed on 02 March 2005".

The Applicant respectfully submits that the filing date of the PCT application is actually February 3, 2005, and not March 2, 2005. For reference, the Applicant has enclosed a copy of the title page of the published PCT application, Pub. No. WO 2005/074367. As indicated at the lines marked "(21)" and "(22)", the International Filing Date of PCT/IL2005/000131 is listed as "3 February 2005 (03.02.2005)".

As noted by the Examiner, Provisional Application 60/541,267 was filed February 3, 2004. This date is one year before the February 3, 2005, filing date of the PCT application. Accordingly, the Applicant submits that it is entitled to claim priority from the above provisional application, and respectfully requests that this priority be entered into the record.

Double Patenting

The Examiner has advised that "claims 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 11/048,807". The Examiner further noted that "this is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented" (emphasis in original).

The Applicant wishes to thank the Examiner for bringing this matter to its attention. In response, the Applicant advises that if the above Application No. 11/048,807 (Applicant's file no. 34952) issues with similar claims, the Applicant plans on filing a terminal disclaimer.

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Amendments To The Claims

The Applicant has amended claims 6, 11, 17, and 19, to correct for informalities in accordance with the Examiner's request in paragraph 3 of the office action. Claim 17 has also been amended to refer to "a setting of said flow regulation mechanism" to correct for a previously missing antecedent for "setting".

In accordance with the Examiner's comments in the Interview noted above, the Applicant has also amended claims 1 and 17, and associated dependent claims 4 and 19, respectively, by replacing the reference to "lumens" with "chambers of a heart". Support for this amendment may be found, for example, in paragraph [0035], lines 4-8, which state "DPRD 101 may be implanted between two or more body lumens, for example, between a left atrium 102 and a right atrium 103 of heart 102. DPRD 101 may be implanted in other heart chambers, using different arrangements of heart chambers, and/or in or between other body lumens."

The Applicant respectfully submits that the above claim amendments are cosmetic, and accordingly do not change the scope of the claims or add new matter to the application.

Claim Rejections under 35 U.S.C. § 102

In paragraph 6 of the Office Action the Examiner states that "Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (U.S. PGPub 2002/0165606)".

The Applicant has amended independent claims 1 and 11 to include the limitation that the adjustable flow regulating mechanism keeps the cover of the shunt always ajar, so that there is a continuous flow of fluid through the shunt. Independent method claim 17 has also been amended, so that the in-vivo pressure control method further includes the step of "maintaining a flow between said chambers through all pressure differences between said chambers".

Support for these amendments may be found throughout the specification. For example, in paragraph [0045] a flow regulation mechanism ("FRM 108") is described

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as being "configured to be constantly ajar at opening 125 to enable a continuous blood flow through shunt 122. For example, in the various embodiments discussed herein, a device may be set so that no matter what the pressure or pressure differential between chambers, a minimum opening size may be set or flow amount may occur".

Turning now to the cited art Wolf, the Applicant notes that Wolf discloses a conduit and one-way valve for diverting blood from a heart chamber to a coronary artery, to bypass a blockage in the coronary artery. The device accomplishes this by enabling blood to flow from the heart chamber to the coronary artery, and by blocking blood flow in the reverse direction. Accordingly the valve is open to permit flow from the heart to the artery, and closed to prevent backflow from the artery to the heart.

References to this feature of the Wolf device include, for example, in paragraph [0037], lines 5-8: "... a one-way valve is positioned within the conduit to prevent blood from flowing back into the left ventricle of the heart from the coronary artery". In paragraph [0041], the last three lines state: "During diastole, the blood pumped into coronary artery through passageway 8 is blocked by one-way valve 6 from returning to left ventricle LV". Another example is in paragraph [0042], lines 5-8, which state: "the high-pressure blood flow causes the valve 10 to open, while the backflow of blood catches the edges of the valve 10 and causes it to close, stopping the flow" (emphasis added in all examples).

On this basis, it is submitted that Wolf does not teach a device or conduit that is "always ajar", and that enables a continuous blood flow at all times, as now claimed in claims 1, 11, and 17, as amended. As such, it is submitted that Wolf does not anticipate claims 1, 11, and 17, as amended.

The Applicant also submits that claims 1, 11, and 17 are not obvious based on Wolf. As noted above, Wolf repeatedly states that the device blocks flow in the backflow direction, from the coronary artery to the heart. The importance of this feature to the functioning of the Wolf device is highlighted even further by the following additional sample references in the text (emphasis added in all examples):

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- paragraph [0044], with reference to the "flapper valve" embodiment of FIG. 3: "... the backflow of blood causes the flap 14 to shut ... to ensure a proper seal."

- paragraph [0045], with reference to the "semi-circular spheres" embodiment of FIG. 4: "... collapses back to prevent back-flow of blood through the conduit 12."

- paragraph [0047], with reference to the "myocardium" embodiment of FIG. 5: "... during diastole, the edges or free portions of the myocardium MYO come together, closing the passage through the myocardium MYO."

- paragraph [0048], with reference to the "two conduit" embodiment of FIGS. 6A and 6B: "...during diastole ... the two conduits ... are positioned such that the valve 24 remains closed ...".

- paragraph [0050], with reference to the "electrical sensor" embodiment of FIG. 7: "... during diastole, the sensor 30 signals the actuator 36 to allow the valve 32 to close and prevent any backflow of blood."

- paragraph [0051], with reference to the "ball valve" embodiment of FIG. 8: "... the backflow of blood from the coronary artery CA to the left ventricle LV causes the ball 44 to seat against the opening 46, thereby closing the valve 42 and preventing the backflow of blood".

- paragraph [0054], with reference to the "ball-and-cage valve" embodiment of FIG. 10A: "... during backflow of blood from the coronary artery CA to the left ventricle LV, the ball 64 moves toward the base of the cage ... blocking the flow of blood from the coronary artery CA to the left ventricle LV".

- paragraph [0055], with reference to the "tapered conduit valve" embodiment of FIG. 10C: "... during backflow from the coronary artery CA to the left ventricle LV, the ball moves against the base 59 of the conduit to block flow of blood therethrough".

Accordingly, it is submitted that it would not be obvious for a skilled person that knows Wolf, and therefore is attuned to the importance of blocking flow in one direction, to arrive at a conduit device that has a cover that is always ajar and that always has a flow through it, as in the claims as amended of the present invention.

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In conclusion, since Wolf teaches a different device directed to a different function, the Applicant respectfully submits that Wolf does not anticipate claims 1, 11, and 17 under 35 U.S.C. s. 102, nor render them obvious under 35 U.S.C. s. 103. It is further submitted that claims 3-6 and 8-10, 12-16, and 18-19 are patentable by virtue of their dependence on allowable claims 1, 11, and 17, respectively.

The Applicant respectfully suggests that none of the currently amended claims add new matter to the application.

All the matters raised by the Examiner are believed to have been dealt with. In view of the above amendments and remarks it is respectfully submitted that claims 1-19 (excluding cancelled claims) are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

Martin D. Moynihan
Registration No. 40,338

Date: August 28, 2008

Enclosures:

- Petition for Extension (Two Months)
- Letter to Chief Draftsman
- Annotated Drawing Sheets
- Formal Drawing Transmittal Sheet
- Complete Set of Replacement Drawing Sheets
- Reference

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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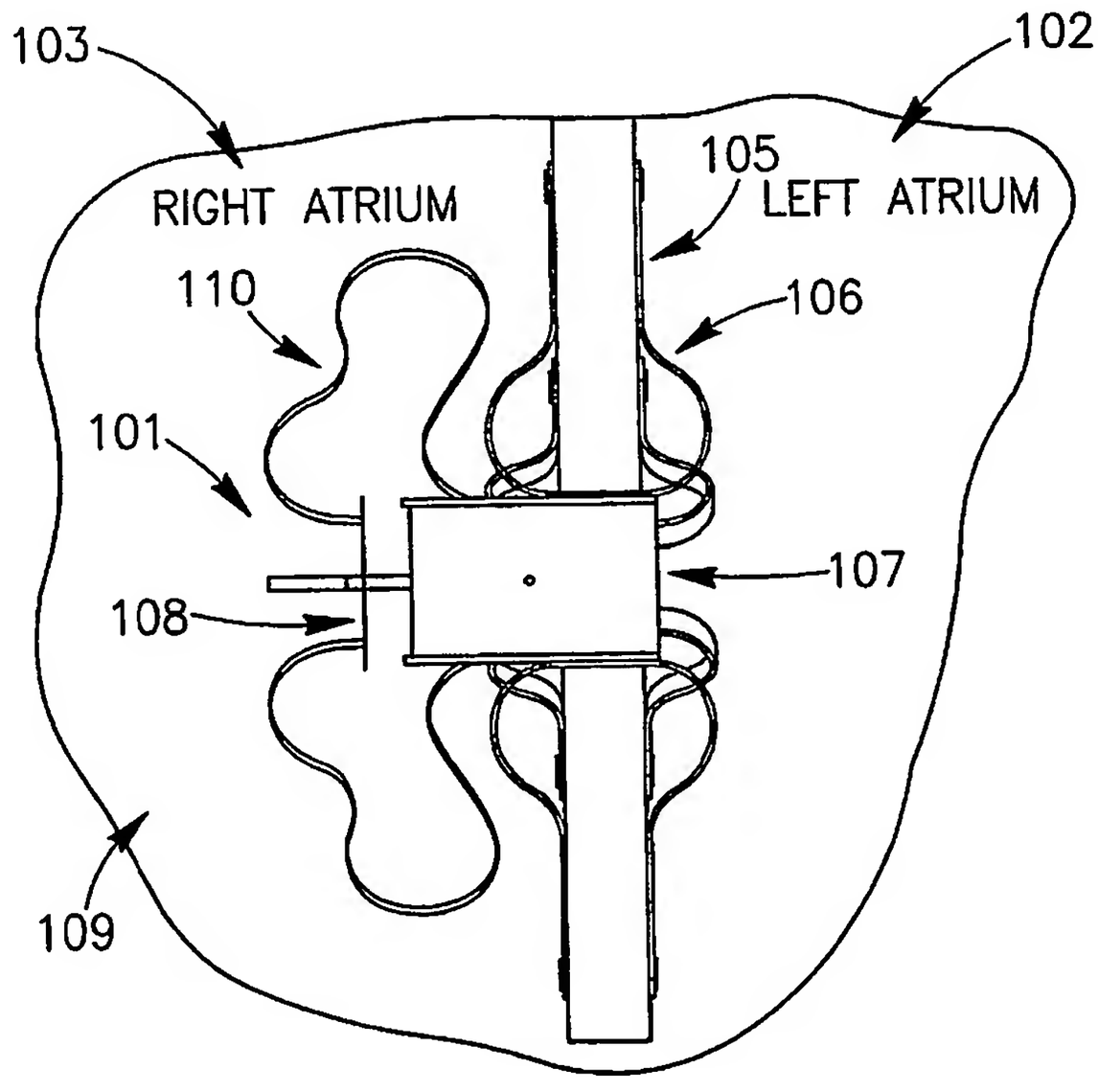
[Continued on next page]

(54) Title: DEVICE AND METHOD FOR CONTROLLING IN-VIVO PRESSURE



(57) Abstract: A differential pressure regulating device is provided for controlling in-vivo pressure in a body, and in particularly in a heart. The device may include a shunt being positioned between two or more lumens in a body, to enable fluids to flow between the lumens, and an adjustable flow regulation mechanism being configured to selectively cover an opening of the shunt, to regulate the flow of fluid through the shunt in relation to a pressure difference between the body lumens. In some embodiments a control mechanism coupled to the adjustable flow regulation mechanism may be provided, to remotely activate the adjustable flow regulation mechanism.

WO 2005/074367 A2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant:		§	
	Dan ROTTENBERG et al	§	
		§	Group Art Unit:
Serial No.:	10/597,666	§	4193
Filed:	June 20, 2007	§	
For:	DEVICE AND METHOD FOR CONTROLLING IN-VIVO PRESSURE	§	Attorney Docket: **34955**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

LETTER TO CHIEF DRAFTSMAN

Sir:

Permission is requested to correct Figure 1A as shown in red ink on the attached photocopy.

Since the foregoing are all relative minor changes and do not include new matter, the formal drawings, which are being submitted herewith in an accompanying letter, include the above-requested changes.

Respectfully submitted,

Martin D. Moynihan

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Date: August 28, 2008

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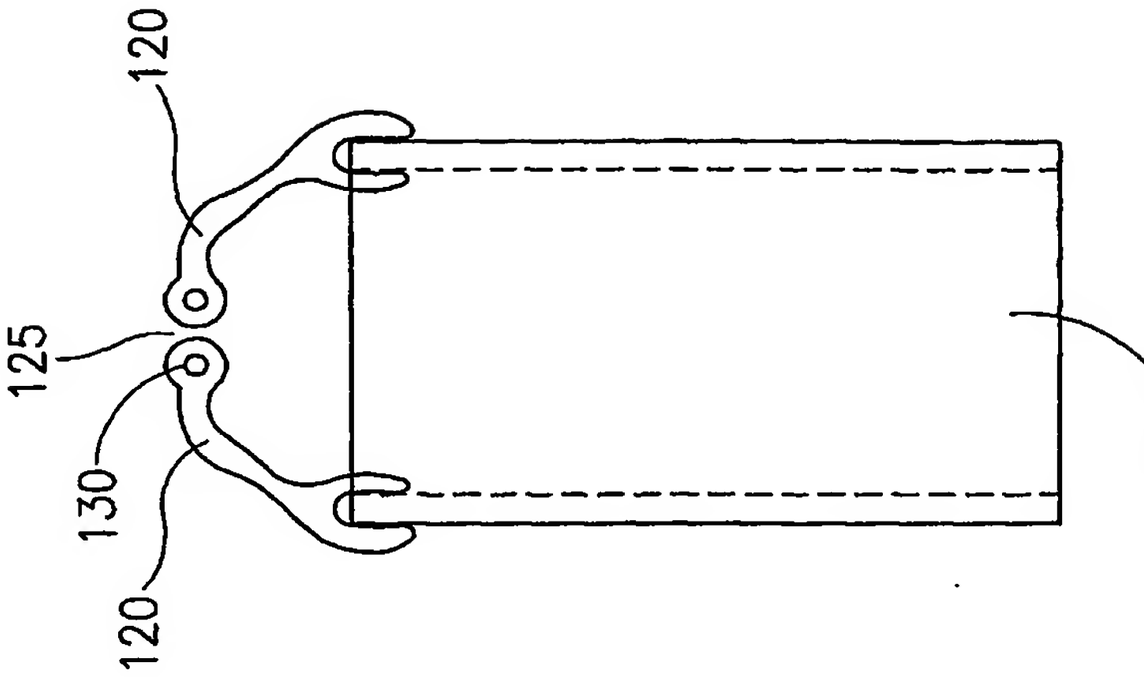

FIG.1B

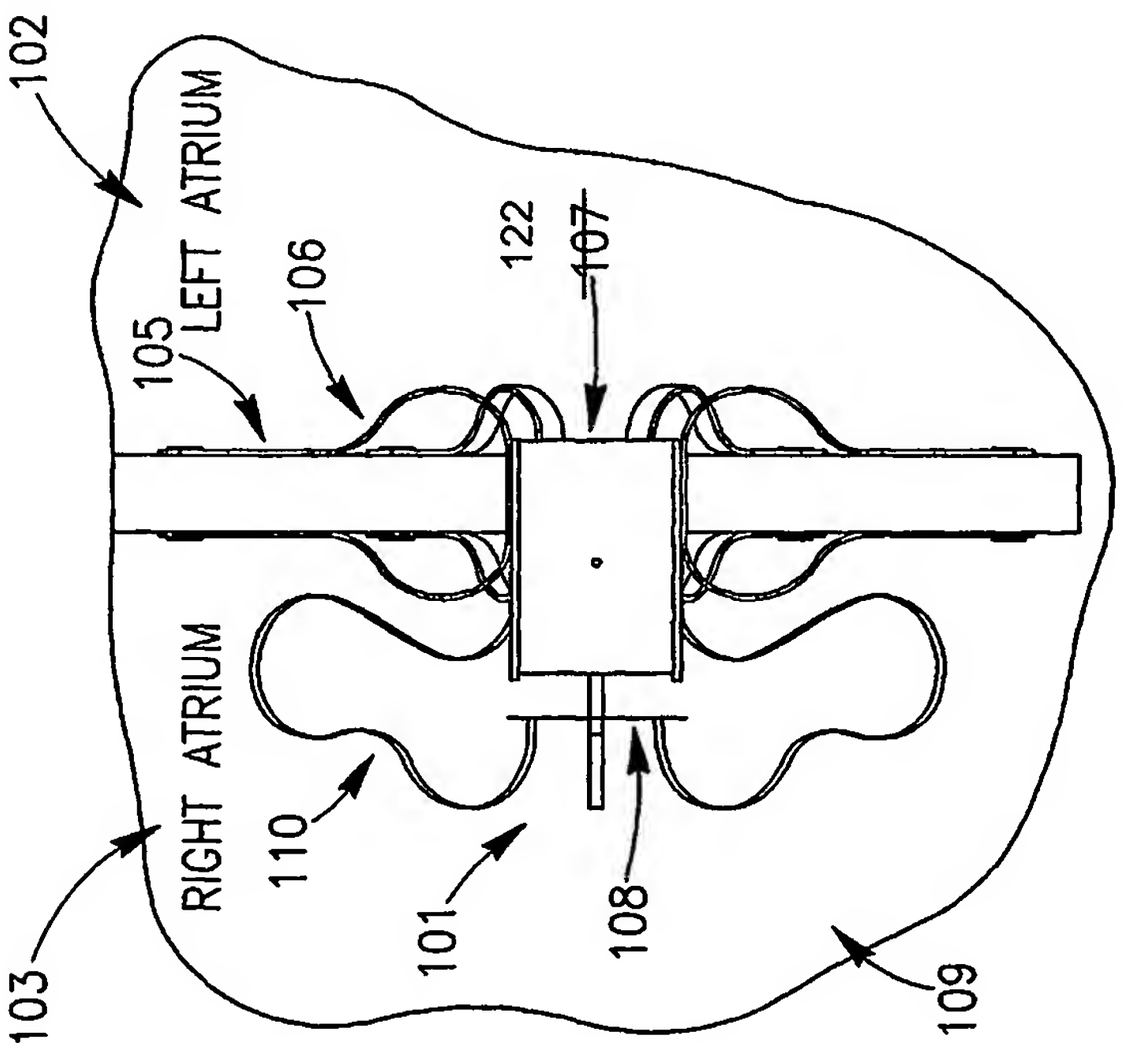

FIG.1A